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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,592	09/30/2003	Sergey Dzekunov	MAXC:014US	9928
32425	7590	07/05/2006		
FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER FERNANDEZ, SUSAN EMILY	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/675,592	DZEKUNOV, SERGEY	
	<b>Examiner</b>	<b>Art Unit</b>	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 17-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed March 29, 2006, has been received and entered.

Claims 1-33 are pending. Claims 17-33 are withdrawn. Claims 1-16 are examined on the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 7 are rendered indefinite by the phrase, "substantially constant". The term "substantially" in claims 1 and 7 is a relative term which renders the claims indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, claims 1-16 are rejected under 35 U.S.C. 112, second paragraph.

Applicant's arguments filed March 29, 2006, have been fully considered but they are not persuasive. Applicant argues that the term "substantially" in claims 1 and 7 would be known to one of ordinary skill in the art. However, it is not clear exactly how much variation is allowable for an electric field to be considered "substantially constant" or exactly what values are considered out of the scope of the term. Applicant points to the page 10, line 28-page 11, line 2

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in the specification as explicit guidelines concerning the term's meaning. However, it is respectfully pointed out that the specification states "...and **in preferred embodiments**, a "substantially constant" quantity is a quantity that has its maximal and minimal values within 50% of its average value during a specified period of time" (emphasis added). This is not an explicit definition of the term "substantially constant" since it only offers a preferred embodiment, and therefore doesn't exclude other interpretations of the term. Thus, the rejection of record must be maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al. (WO 00/37628, English language equivalent US 6,492,175).

Muller et al. teaches a method for electroporation wherein a sample is displaced through a channel, past electroporation electrodes which generate a spatially inhomogeneous electric field in the channel, thus anticipating claims 1, 7, and 8 under examination. See US 6,492,175, claims 14 and 16 and column 2, line 66 through column 3, line 14, in particular column 3, lines 8-10, which discloses the generation of an "inhomogeneous electric field". The electric field can be coupled to a DC source ('175, column 8, lines 54-60) or it can be coupled to an AC source, as Muller et al discloses an alternating field ('175, column 7, lines 61-67 through column 8, line 2).

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Furthermore, the electric field generated may be about 100V ('175, column 3, lines 39-43).

Therefore, Muller et al. also anticipates claims 2, 3, and 11.

Applicant's arguments filed March 29, 2006 have been fully considered but they are not persuasive. Applicant argues that the prior art does not teach the limitations that electroporation is effected by sample displacement. However, as pointed out above, the sample is sent through a channel structure, thus it is displaced, and therefore, electroporation is effected by sample displacement. Additionally, applicant asserts that the electric field is not "substantially constant." Nevertheless, it is respectfully pointed out that "substantially constant" is open to interpretation and can allow up to a large range in variation from an average value of the electric field or continuity of electric field applied to the sample.

Additionally, applicant asserts that the new limitation in claim 1, which requires that "the field is generated with electrodes that are continuously energized at least while the sample traverses the electric field" is not taught by Muller et al. However, it is respectfully pointed out that the requirement that the electrodes are continuously energized does not signify that the electrodes cannot send out electrical pulses. Electrodes connected to a power source can be considered continuously energized, and moreover, even between pulse transmissions, the electrodes still would be considered energized. Thus, a holding of anticipation is clearly required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al in view of Baumann et al. (US 6,368,851) or Acker (US 2004/0029240).

As discussed above, Muller et al. anticipates claims 1-3, 7, 8, and 11. However, Muller et al. does not expressly disclose displacement of electrodes.

Baumann et al. discloses an electroporation device wherein electrodes connected to an electric voltage source are moved with respect to a stationary specimen (see claims 4 and 9).

Acker discloses a method of electroporation wherein a target cell, which is considered within a sample, is placed into a sample gap between two electrodes which are displaced (claim 11). During electroporation, the target cell may be displaced as it changes orientation (page 9, paragraph [0124]). However, the sample is still considered stationary.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified the Muller invention such that the electrodes are displaced during electroporation while the sample being electroporated is displaced or maintained at a stationary position. One of ordinary skill in the art would have been motivated to do this since movement of the electrodes has been shown to be effective in electroporation (Baumann et al. and Acker) and it would have further contributed to generating an inhomogeneous electric field necessary to create negative dielectrophoresis required by the Muller invention. Furthermore, Acker points out that electroporation involving displacement of electrodes "...has the advantage of obtaining high yields of electroporated cells due in part to the ability to create randomly rotating cell

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conditions” (page 4, paragraph [0072]). Additionally, this method “...avoids repeated pulsing into already opened pores and possible destruction of the molecules or cells” which “enables maximum transfer rates of material into cells with minimum cell loss”. One would have clearly been motivated to displace electrodes when performing electroporation taught by Muller et al., whether during electroporation the sample is in motion (‘175, claim 16) as required by instant claim 10 or stationary (‘175, claim 17) as required by instant claim 9.

Muller et al. also does not disclose the power consumptions, duty cycles, and AC frequencies recited in claims 4-6, 12, and 14-16. Nevertheless, the selection of specific suitable peak and average power consumptions, duty cycles, and AC frequencies, including those claimed, clearly would have been an obvious matter of optimization on the part of the artisan of ordinary skill. Furthermore, though Muller et al. does not disclose specifics as to electrical power sources, it would have been obvious to have used any electrical power source, including a standard electrical wall outlet which is known as a common, accessible source. Thus, claim 13 is rendered obvious.

Applicant's arguments filed March 29, 2006, have been fully considered but they are not persuasive. As discussed above, the displacement of the pair of electrodes and a sample relative to one another is taught by the references since Muller et al. indeed teaches that the sample is displaced and since Baumann et al. and Acker teach displacement of electrodes for electroporation. Since there is displacement, electroporation would as a result be effected by it. Though Baumann et al. teaches immobilization of cells to be electroporated, the Baumann reference is provided to demonstrate the benefit of displacing electrodes for electroporation. Acker also served this purpose.

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Thus, a holding of obviousness is clearly required.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

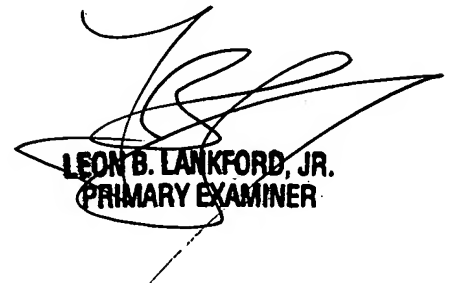


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan E. Fernandez  
Assistant Examiner  
Art Unit 1651

sef



**LEON B. LANKFORD, JR.**  
**PRIMARY EXAMINER**